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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,990	HEIRLER, HORST	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 9-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6 and 9-21 are presented for examination.

Applicant is notified that the finality of the previous Office Action dated September 28, 2009 is hereby withdrawn. The after-final amendment filed December 28, 2009 was timely filed and fully responsive to the prior Office Action and has been entered into the record. Prosecution of the present application has been reopened.

The Notice of Appeal dated March 26, 2010 is moot in view of the new grounds of rejection *infra*.

Applicant's after-final amendment filed December 28, 2009 has been received and entered into the instant application.

Claims 1, 3-6 and 9-21 remain pending and under examination. Claim 22 is cancelled.

Applicant's arguments and amendments, filed December 28, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6 and 9-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Present claim 1 is directed to a method for supplementing the diet of a subject with diabetes mellitus comprising administering to the subject a composition comprising, *inter alia*, 0.5 to 2% eicosapentaen acid and/or docosahexaen acid as multiple unsaturated triglycerides.

In particular, it is unclear what is meant by the phrase "multiple unsaturated triglycerides" as used in the instant claims. For example, the claim fails to clearly set forth whether the term "multiple" is intended to mean that the composition contains more than one “unsaturated triglyceride” of EPA and/or DHA or if it is intended to mean that the triglycerides contain multiple sites of unsaturation (i.e., “polyunsaturated” triglycerides of EPA and/or DHA). Neither the claims nor the specification clearly describe what is meant by the phrase "multiple unsaturated triglycerides" and, thus, the phrase renders the instant claims indefinite for this reason. As a result, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6, 9, 14-19 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0690179 A2; 1996) in view of Horrobin (U.S. Patent No. 6,479,544; November 12, 2002).

Alexander et al. teaches an enteral composition for providing nutrition or nutritional supplementation to a diabetic patient (abstract; p.2, l.25-26) that reduces the sensitivity to dose and timing of insulin to reduce the post-prandial serum glucose via improved tolerance, metabolic and glucose management and insulin requirements (p.3, l.55-58), which contains: (1) a fat source comprising medium

chain triglycerides (20% of the fat source) and long chain triglycerides, which are preferably provided as, e.g., hi-oleic safflower oil or hi-oleic sunflower oil, of which such oils further provide for essentially fatty acids linoleic and linolenic acid in an amount of 4-10% (p.4, l.10-26), (2) mono-unsaturated fatty acids (p.4, l.29-34), (3) a protein component (p.4, l.34-35), (4) a carbohydrate component (p.4, l.36-40), (5) flavoring, i.e., vanilla (Table, p.6), and (6) various vitamins and minerals, including vitamin A, beta-carotene, vitamin D, vitamin E, vitamin C, folic acid, vitamin B6, vitamin B12, thiamine (i.e., vitamin B1), riboflavin (i.e., vitamin B2), niacin, zinc, chromium, or manganese (Table, p.6-7). Alexander et al. teaches the use of water for formulating the disclosed product (Table, p.7).

Alexander et al. fails to teach (1) the amount of saturated long-chain triglycerides of 6% at most (claim 9); (2) the amount of fat phase versus aqueous phase (claim 14); (3) the amount of zinc and/or chrome and/or manganese per 100 g of the composition (claim 19) or (4) the inclusion of eicosapentaen and/or docosahexaen acid (claim 1) and wherein that the eicosapentaen and/or docosahexaen acid are from refined fish oil concentrate (claim 21).

Regarding (1), the amount of saturated long-chain triglycerides of 6% at most (claim 9), the claimed amounts of medium-chain triglycerides (10-30%) versus saturated long-chain triglycerides (0.5-6%) (see, e.g., present claim 9), one of ordinary skill in the art would have found it *prima facie* obvious to increase the amount of medium chain triglycerides (MCTs) relative to the amount of long-chain triglycerides (LCTs; i.e., reduce and minimize the amount of LCTs) because, as Alexander et al. explicitly teaches, MCTs aid in digestion; digestion of MCTs is easier than LCTs because LCTs are digested by various lipases that are not required to digest MCTs; absorption of MCTs is faster than LCTs because LCTs require incorporation into chylomicrons by intestinal mucosal cells; and LCTs are oxidized more slowly and require carnitine for entry into the mitochondria (p.4, l.16-20). Such a person would have been clearly motivated to do so in order to reduce the elapsed time from administration to therapeutic effect in the patient being treated so as to provide rapid nutritional supplementation.

Further, regarding (2), the amount of fat phase versus aqueous phase (claim 14), Alexander et al. teaches formulation of the disclosed product in a water vehicle, which is clearly indicative of the fact that the overall enteral formulation would, at least prior to mixing, necessarily have a fat phase containing the fat source(s) and an aqueous phase containing the water solvent. Accordingly, though Alexander et al. does not explicitly acknowledge such a characteristic of the disclosed formulation, such a property is considered to be necessarily present, absent factual evidence to the contrary. Moreover, it logically follows, and would have been readily apparent to the skilled artisan, that the presence of various fat-soluble and water-soluble vitamins and minerals would necessarily mean that each would be found in the phase in which they were soluble, e.g., the fat-soluble vitamin A would be found in the fat-phase, whereas the water-soluble vitamin B6 would be found in the aqueous water phase. The determination of the optimal ratio of fat phase to water phase (i.e., fat=80%, aqueous=20% or fat=60-65%, aqueous=35-40%) would have been directly dependent on the amount of fat necessary to treat the patient and the amount of water needed to prepare the formulation and maintain the desired osmolality of the solution. Accordingly, the ratio of fat phase to aqueous phase would have been reasonably expected to vary widely by individual to be treated and, in the absence of evidence to the contrary, the currently claimed ratios are not seen to be inconsistent with those that would have been determined by, well within the skill of and, therefore, *prima facie* obvious to, the skilled artisan.

Regarding (3), the amount of zinc and/or chrome and/or manganese per 100 g of the composition (claim 19), the claimed dosage amounts of the various vitamins and minerals, the determination of the optimum dosage amounts of the presently claimed active components would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed,

whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the dietary needs of the patient being treated. Thus, the amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentrations of the active ingredients are result-effective variables, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable ranges would have been well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). As taught by the MPEP at §2144.05, "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Horrobin teaches a formulation of essential fatty acids, comprising eicosapentaenoic acid (EPA) in a biologically assimilable form, such as in the form of, *inter alia*, triglycerides (i.e., which is understood to be a "multiple unsaturated triglyceride" because EPA is described as "polyunsaturated", see col.1, l.15-19 and l.60-67; col.2, l.55-57) wherein the EPA is at least 50%, preferably at least 90% pure, with arachidonic acid (col.2, l. 36-40). Horrobin discloses administration of the EPA formulation for the treatment of, *inter alia*, diabetes (col.3, l.1-27) and teaches that it may be administered orally (col.4, l.56-59), including in the form of flavored oil blends, etc. (col.4, l. 59-62). Horrobin teaches that the EPA may be derived from, *inter alia*, marine oils from fish or other marine animals (col.4, l.41-44).

One of ordinary skill in the art would have found it *prima facie* obvious to combine the formulation of Alexander et al. useful for the treatment of diabetic patients by improving glucose tolerance, metabolic and glucose management and insulin requirements with the EPA formulation also known to be effective for treating diabetic patients, as evidenced by Horrobin, as an effective treatment

for diabetes, because each pharmaceutical agent was known to have therapeutic efficacy in the treatment of diabetes. Motivation to administer the compounds together flows logically from the very fact that each agent was known in the prior art to have the same therapeutic utility and, in turn, raises the reasonable expectation of success that the two compounds, when combined, would have, at minimum, additive, if not synergistic, effects in treating a diabetic patient. Please see *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980) ["It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."] and *In re Diamond and Kellman*, 149 USPQ562 (CCPA 1966).

Lastly, regarding (4), that the eicosapentaen and/or docosahexaen acid are from refined fish oil concentrate (claim 21), though it is noted that Horrobin does teach that EPA may be derived from marine oils from fish or other marine animals (col.4, l.41-44), but does not explicitly teach that the docosahexaen and/or eicosapentaen acid is from refined fish oil concentrate as instantly claimed, Applicant is reminded that this limitation is a process limitation (i.e., directed to a process of obtaining docosahexaen and/or eicosapentaen acid from refined fish oil concentrate) and, thus, fails to materially or structurally limit the claimed fatty acids as a whole since the prior art already teaches the obviousness of the instantly claimed product. Accordingly, since the cited reference(s) clearly renders obvious the same combination of the claimed components, the process Applicant intends to prepare the claimed composition is immaterial to the composition as a whole. As directed by the MPEP at §2113, "Even though product-by-process claims are limited by and defined by the process, *determination of patentability is based on the product itself.* The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" (see *In re Thorpe*, 777 F.2d 695, 698, 227

USPQ 964, 966 (Fed. Cir. 1985 and MPEP §2113)). Moreover, MPEP §2113 states, "Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product."* (emphasis added)

Claims 1, 3-6, 9-10 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in view of Horrobin (U.S. Patent No. 6,479,544; November 12, 2002), further in view of Madigan et al. ("Dietary Unsaturated Fatty Acids in Type 2 Diabetes", *Diabetes Care*, 23:1472-1477; 2000), Heine et al. ("Linolenic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients", *Am J Clin Nutr*, 1989 Mar; 49(3):448-456; Abstract Only) and The Merck Index ("Citric Acid", Monograph 2328, 1989; p.363).

Alexander et al. in view of Horrobin as applied *supra*.

Alexander et al. in view of Horrobin fail to further teach (1) the use of 20-60% oleic acid as monounsaturated triglyceride (claim 4); (2) the use of 10-35% linoleic acid as double-unsaturated triglyceride (claim 5); or (3) the use of citric acid (claim 20).

Heine et al. teaches that linoleic acid-enriched diets in patients with non-insulin dependent diabetes causes a less atherogenic lipoprotein profile, but does not influence glycemic control and carbohydrate tolerance (abstract).

Madigan et al. teaches a comparative study of subjects suffering from Type 2 diabetes, wherein one cohort of patients was treated with a linoleic acid-rich diet and another cohort of patients was treated with an oleic acid-rich olive oil diet (abstract). Madigan et al. teaches that the Type 2 diabetes patients fed a linoleic acid-rich diet had higher fasting blood glucose and insulin levels, higher plasma cholesterol

and LDL cholesterol and higher fasting and postprandial chylomicron and VLDL apoB48 and apoB100 than those fed an oleic-acid rich diet. Madigan et al. teaches that the decrease in the number of chylomicron remnant particles in those subjects fed an oleic acid-rich diet may reduce the risk of atherosclerosis (abstract).

In view of such teachings, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to use linoleic acid as a major component (e.g., 10-35%) of the disclosed diabetic supplement composition. Such a person would have been motivated to do so because linoleic acid-rich diets were known to exert an anti-atherosclerotic effect in patients suffering from Type 2 diabetes, which was a known, and deadly, complication of Type 2 diabetes. The skilled artisan would have incorporated linoleic acid with the reasonable expectation of success that the addition of such an acid in such a quantity would have conferred such an anti-atherosclerotic property to the composition.

Furthermore, one of ordinary skill in the art at the time of the invention would have also found it *prima facie* obvious to also add oleic acid in a significant quantity of the total composition (i.e., 20-60%) of the disclosed diabetic supplement because oleic acid-rich diets were also known to reduce atherogenic risk in a manner similar to linoleic acid-rich diets. The very fact that both linoleic acid-rich diets and oleic-acid rich diets were known to have the same therapeutic effect of reducing atherogenic risk in patients with Type 2 diabetes raises the reasonable expectation of success that the two acids, when combined, would have, at minimum, additive, if not synergistic, effect in reducing atherogenic risk in diabetic patients when combined. Please see *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980) ["It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."] and *In re Diamond and Kellman*, 149 USPQ562 (CCPA 1966).

Moreover, one would also have been motivated to provide more oleic acid than linoleic acid because oleic acid was known in the art to have an additional therapeutic benefit over linoleic acid, namely, that oleic acid was known to reduce atherogenic risk *and* also reduce blood glucose and insulin levels, where linoleic acid was only known to be capable of reducing atherogenic risk in the absence of any effect on glycemic control or carbohydrate tolerance. Accordingly, the inclusion of oleic acid in greater quantity than linoleic acid would have been reasonably expected to increase the anti-atherosclerotic properties of the composition, as well as to assist the diabetic patient in maintaining proper glycemic control.

Regarding the specifically claimed ranges of linoleic acid and oleic acid (10-35% and 20-60%, respectively), it is further noted that the determination of the optimum dosage amounts of the presently claimed active components would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the dietary needs of the patient being treated. Thus, the amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentrations of the active ingredients are result-effective variables, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable ranges would have been well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). As taught by the MPEP at §2144.05,

"Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

The Merck Index teaches that citric acid is a commonly used acidulant for pH adjustment and as a flavor enhancer (Monograph 2328; p.363).

Lastly, one of ordinary skill in the art would have found it *prima facie* obvious to incorporate citric acid into the disclosed diabetic supplement because, as taught by The Merck Index, citric acid is a commonly used acidulant for pH adjustment and also to enhance flavor. Such a person would have been motivated to do so in order to arrive at a pharmaceutically acceptable pH value and also to enhance the palatability of the composition.

Claims 1, 3, 6, 9, 11-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in view of Horrobin (U.S. Patent No. 6,479,544; November 12, 2002) further in view of Bell et al. (WO 97/38593; 1997) and Mendy (U.S. Patent No. 4,407,821; 1983), each already of record.

Alexander et al. in view of Horrobin as applied *supra*.

Alexander et al. in view of Horrobin fail to further teach (1) the use of butter flavoring (claim 11) or (2) the use of, e.g., vitamin C in the form of ascorbyl palmitate in the claimed amount (claims 12-13).

Bell et al. teaches a diabetic supplement used for treating diabetic patients, wherein the supplement includes various flavorings, such as, e.g., chocolate flavoring, peanut butter flavoring, etc., or any commercially available flavoring, to enhance palatability (p.5, l.3-9).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to incorporate any one or more of known commercially available flavorings, such as, e.g., peanut butter flavoring, etc., to enhance the palatability and deliciousness (as evidenced by Bell et al.) of the product suggested by the cited prior art. Such a person would have been motivated to do so in order to

improve the taste and flavor of the composition so as to make it more desirable and pleasing to the consumer, as well as to improve patient compliance with a regimen of administration as a result of superior taste.

Mendy teaches the pharmaceutical use of vitamin C in the liposoluble form of ascorbyl palmitate for incorporation into a lipid composition for the treatment of diabetics (col.5, l.35-37 and 54-57; col.6, l.29-33).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to incorporate vitamin C in the form of ascorbyl palmitate because such a form of vitamin C was known to be fat-soluble, as evidenced by Mendy, and, thus, would be amenable to incorporation into a lipid composition, such as that suggested by the cited prior art. Such a person would have been motivated to do so in order to effect homogenous solubilization of the vitamin C component into the lipid components of the disclosed composition.

Furthermore, regarding the specifically claimed amount of, e.g., ascorbyl palmitate, as recited in instant claim 13, it is again noted that the determination of the optimum dosage amount of the presently claimed active component(s) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized, whether the compound is administered as part of a drug combination and the dietary needs of the patient being treated. Thus, the amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentrations of the active ingredients are result-effective variables, i.e., a

variable that achieves a recognized result, and, therefore, the determination of the optimum or workable ranges would have been well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). As taught by the MPEP at §2144.05, "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Conclusion

Rejection of claims 1, 3-6 and 9-21 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

March 31, 2010